

REMARKS

The Examiner states that the fused junctures are not describe in the specification as being "non-inflatable". The Applicant respectfully disagrees. The specification states in paragraph 0036 as follows:

"Fig 1F also illustrates the junctures 14 to be very small in width (about one millimeter) 29. They serve both as (a) conduit that connects the adjacent chamber 16 through multiple holes 19 within, and as bending areas *(as they do not expand or pressurized when the graft is fully inflated)* thus giving the graft some flexibility between the fully inflated segments 17A, 17B, 17C, 17D, and 17E; allowing it to conform to the shape of the blood vessel without the risk of kinking or distortion."
(emphasis supplied.)

The above quoted text makes clear that the junctures are not inflated, i.e., they do not expand nor are they pressurized when the graft is fully inflated. Obviously an object is pressurized when inflated. The fused juncture is not pressurized and hence not inflated.

In response to the Examiner's objection to the term "web reinforcement", the Applicant has substituted the term "web support". Paragraph 0031 of the specification states "(t)he walls are also interconnected by network of integral radially oriented *support or retention webs.*" (emphasis supplied.)

The Examiner also objects to the specification based upon the assertion that the specification does not provide an antecedent basis for the claimed feature "fluid impermeable" seal of the first outer wall and the second inner wall. The Applicant respectfully disagrees with the Examiner. In discussing the inner and outer walls of the graft, paragraph 0030 of the specification states: "*(t)he two walls 12 13 are completely sealed together both distally and proximally to form the fluid tight chambers 16* that is only attached to, and in fluid communication with, the smaller lumen of the delivery catheter through a detachable check valve 10." (emphasis added) However, to expedite the allowance of the claims, the phrase "fluid tight" has been substituted for fluid impermeable.

The Examiner has rejected the claims on the basis of 35 USC §112, first paragraph, on the basis that the description fails to comply with the written description requirement. The Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time of the application was filed, had possession of the claimed invention.

It is useful to note that the written description requirement and the enablement requirement "usually rise and fall together". That is, the recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possess the full scope of the invention and vice versa." LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 76 U.S.P.Q. 2d 1724 (Fed. Cir. 2005). There has been no question that the specification fails to enable a person skilled in the art to practice the invention.

Specifically, the Examiner has rejected claims 1, 33, 38, and 42 on the basis that the specification does not describe or support the limitation that the web supports are "non-elastic" or "inelastic". It is the Applicant's position that the specification does teach a non-elastic web support. The specification at paragraph 0034 states "FIG. 1E illustrates an axial cross section of a chamber of the invention, illustrating *the multiple webs 20 that may be used to join the two walls together throughout the circumference of the chamber. This configuration ensures that the graft thoroughly inflates to a pre-selected shape without distortion; ...*" (emphasis added)

The web support functioning as described above, could only be inelastic. A structure that is stretched by fluid pressure would distort, i.e., to twist out of a natural, normal, or original shape or condition. Merriam Webster Online Dictionary. Distort is a synonym of deform. Merriam Webster Online Dictionary. Deform means to alter the shape of by stress. It is the Applicant's position that "non-deforming" web support would be synonymous with "non-elastic web support." Further, a person skilled in the art would understand from the specification that the web support must be inelastic in order for the graft to inflate to a pre-selected size and shape.

In order to improve the efficiency of the claim approval process, the Applicant has adopted "non-distorting web reinforcement."

The Examiner has rejected claim 1 on the basis that the specification does not describe the fluid chambers as "non-elastically extensible". The Applicant disagrees. The fluid chambers are formed from the space between the double walled graft made of non-compliant material. See paragraph 0028. Compliance means the *extension or displacement* of a loaded structure per unit load. See American Heritage College Dictionary, 3rd Ed. A material that is elastic can not be non-compliant since elastic material is defined to be material that easily resumes its original shape after being stretched or expanded. American Heritage College Dictionary, 3rd Ed.

However, solely to expedite allowance of claim 1, the Applicant has substituted "non-compliant" for non-elastically extensible.

The walls of the fluid chamber are defined in the specification as not extending or being displaced when subject to fluid pressure. The chambers are defined as not becoming distorted when inflated. See paragraph 0030 of the specification. Therefore, the fluid chambers are non-elastic.

The Examiner has rejected the "acute angle" of the tapered fused juncture as not being described in the specification. The tapered walls forming acute angles with the inner wall are clearly shown in Figure 1F. The text of the specification at paragraph 0036 is amended in accordance with 37 CFR 1.75, MPEP §608.01(i) and §1302.01.

The Examiner has rejected claim 4 stating there is no support for a "variably sized" width of a fused juncture. It is the Applicant's position that the Examiner is incorrect. Paragraph 0036 of the specification states. "(i)t will be appreciated that the *design selection of the segments and junctures may facilitate deployment of the device within varying vessel diameters, tissue structure or architecture.*" It is the Applicant's position that this sentence includes a design of a fused juncture having a variable width to allow the inflated graft to conform to a curved vessel, i.e., varying vessel architecture. 35 USC §112, 1st paragraph, states that the written description requirement must enable any person skilled in the art to which it pertains. In the instant case the person skilled in

the art would include a neurovascular surgeon. The text of the specification meets the enablement and the description requirement.

In regard to claim 33, the Examiner asserts that the specification does not describe in accordance with 35 USC §112, 1st paragraph, that "a graft having an inflated diameter compatible with an un-diseased body lumen and a length greater than the diseased portion of said cerebral vessel lumen" or that "the graft contacts an un-diseased portion of the cerebral vessel lumen."

The specification states in paragraph 0003 "(t)he invention pertains to a graft design that combines the minimal size and increased flexibility in its deliverable form which allows for successful navigation of torturous, stenotic blood vessels, aneurysm and other body passages with an in situ increase in size and rigidity, thus improving upon the current covered stent in treatment of various diseases such as atherosclerosis and aneurysm."

At paragraph 0006, the specification states "(d)evices for treatment of aneurysms may not provide sufficient wall support or, alternatively, have material properties hindering their deployment within the affected portion of a vessel. Other devices may be subject to dislocation by the mechanics of fluid flow and pressure. Further, other devices of treating aneurysms, such as coils, are not suitable for certain types of aneurysm, e.g., wide neck or fusiform aneurysms. They may also be subject to incomplete obliteration of the aneurysm or coil compaction which may result in re-growth of the aneurysm and future rupture."

At paragraph 0009, the specification states "(t)he invention also pertains to a method and apparatus for repairing aneurysm vessels by providing a graft design that, when *deployed across the aneurysm*, will effectively exclude the aneurysm from circulation and reinforce the weak blood vessel wall. This minimizes possible re-growth or recanalization. It will be appreciated that the operation of the invention reinforces the blood vessel wall both at the location of the aneurysm and in the proximate surrounding area." (emphasis added)

Paragraphs 0042 and 0043 of the specification state in their relevant part "(a)fter the graft expands to its predetermined shape and size 26, a slight increase in the

amount of the injected material will lead to increased pressure inside the graft, and exert a sufficient radial force outward, thus becoming axially and sealingly fixed to the inside of the blood vessel.

"The graft can then be detached from the delivery catheter 27 through the detachable valve leaving the graft fully expanded and pressurized. This graft design functions as a covered stent graft for treating diseases such as atherosclerosis and aneurysms."

Again the description required of 35 USC §112, 1st paragraph, must enable a person skilled in the technology to make or use the invention. The specification states the graft is deployed *across the aneurysm* and thereby *effectively excludes the aneurysm from circulation*. Therefore the specification requires the graft to be longer than the diseased vessel section. The specifications further states the graft is inflated to a predetermined size and shape and *fixed to the vessel including the area proximate to the diseased area*. The graft is therefore fixed to the un-diseased vessel wall. As would be readily understood by a persons skilled in the art, the aneurysm is a ballooning outward of the vessel wall. The inflatable graft is not selected to match the diameter of the diseased ballooned wall but rather the un-diseased portion of the vessel wall. This would be consistent use of prior art metal stents.

The Examiner states "side fenestrations are not described in the written description or the drawings, other than a nominal recitation of the terms 'side fenestrations'. It is the Applicants position that a side fenestration is readily understood by a person skilled in the art. The specification states in the relevant part of paragraph 0036 "(i)t will be appreciated that the design selection of the segments and junctures may facilitate deployment of the device within varying vessel diameters, tissue structure or architecture. In other embodiments, side fenestrations may be created at selected locations of the invention to allow deployment of across bifurcating blood vessel without compromising blood flow."

It is clear from reading the above text that a side fenestration is an opening in the wall of the graft to allow blood to flow through a branch vessel. The placement and size of such a side fenestration can be specified with the design of the graft.

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GAU 3738
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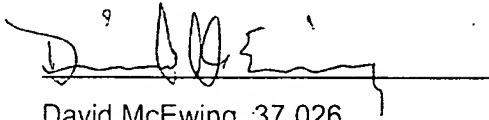
The Applicant has cancelled claim 47 pertaining to a dimpled outer wall of the graft.

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SUMMARY

The Applicant has amended the claims to meet the objections of the Examiner. One claim has been cancelled. The Applicant has also made specific reference to paragraphs of the specification containing text describing the invention claimed.

The Applicant believes the remaining claims are allowable and such action is respectfully requested.

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David McEwing, 37,026

PO Box 231324

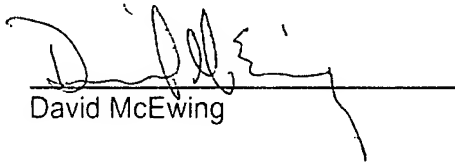
Houston, TX 77223

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CERTIFICATE OF TRANSMISSION

The undersigned certifies this Response to Office Action was transmitted to the Commissioner of Patents, Box 1450, Alexandria, VA 22313-1450 on September 23, 2008 via EFS-Web.

A handwritten signature in black ink, appearing to read 'D. McEwing', is written over a horizontal line.

David McEwing